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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,427	07/17/2003	Dileep Bhagwat	025562.0009-US01	1102
26853	7590	06/05/2006	EXAMINER	
COVINGTON & BURLING ATTN: PATENT DOCKETING 1201 PENNSYLVANIA AVENUE, N.W. WASHINGTON, DC 20004-2401			HUI, SAN MING R	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 06/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/620,427	Applicant(s) BHAGWAT ET AL.	
	Examiner San-ming Hui	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7-17-03</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

THIS APPLICATION IS A CONTINUATION OF us Serial 09/998,537, filed 11/28/2001, now abandoned.

Claims 1-16 are pending.

Claim Objections

There are two claims 15 in the application. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/756,354 ('354) in view of Perricone (WO 98/23152). Although the conflicting claims are not identical, they are not patentably distinct from

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each other because the range of urea recited in '354 are closely overlapped with the herein claimed amount of urea. '354 does not expressly teach propylene glycol as one of the excipients. Perricone teaches a topical composition comprising i) urea and ii) vitamin E, or ascorbyl palmitate, or vitamin C, and iii) grape seed extract (See page 13, line 9-28; also claims 1, 3, 9, and 13). Perricone teaches the wt.% of ascorbyl palmitate to be 2% to 15% (See particularly claim 15). Perricone also teaches the wt.% of propylene glycol to be 3.00% (See particularly page 13, line 15).

Therefore, It would have been obvious to one of ordinary skill in the art at the time of invention to employ the herein claimed excipients into the composition of '354.

Incorporating well-known excipients into a composition is routinely practiced and thus, obvious, absent evidence to the contrary.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter et al. (US Patent 5,968,533) and Valdez et al. (US Patent 5,919,470) in view of Perricone (WO 98/23152) and Gennaro (Remington's Pharmaceutical Science, 18th ed., 1990, page 1305, 1310, 1317, 1323, and 1329), references of record.

Valdez et al. teaches a dermatological composition useful in treating dry skin containing 21-40% of urea (See particularly the abstract).

Porter et al. teaches that vitamin E is useful in treating dry skin condition (See col. 2, line 44 – 48).

The references do not expressly teach the vitamin E and urea to be useful together in a composition or method to treat dry skin. The references do not expressly teach the incorporation of the herein claimed topical excipients, in the herein claimed amount.

Perricone teaches a topical composition comprising i) urea and ii) vitamin E, or ascorbyl palmitate, or vitamin C, and iii) grape seed extract (See page 13, line 9-28; also claims 1, 3, 9, and 13). Perricone teaches the wt.% of ascorbyl palmitate to be 2% to 15% (See particularly claim 15). Perricone also teaches the wt.% of propylene glycol to be 3.00% (See particularly page 13, line 15).

Gennaro teaches petrolatum is a common base useful in topical dosage formulations (See page 1310, col. 1). Gennaro also teaches carbomer and

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triethanolamine are common emulsifying agents (See particularly page 1305, col. 1 and page 1317, col. 1 to col. 2). Gennaro teaches mineral oil as commonly known as vehicle (See page 1323). Gennaro also teaches urea is useful in treating dry skin and that the concentration of urea used in dry-skin cream is 2 to 20% (See page 1329, col. 2).

It would have been obvious to one skill in the art when the invention was made to incorporate vitamin E and 21 to 40% of urea into the composition to treat dry skin. It would have been obvious to one skill in the art when the invention was made to employ the herein claimed excipients into the composition and method of treating dry skin.

One of ordinary skill in the art would have motivated to incorporate vitamin E and 21 to 40% of urea into the composition to treat dry skin and employ the composition herein in a method of treating dry skin because both urea and vitamin E are known to be useful in treating dry skin. Employing both active agents which are known to be useful to treat dry skin individually in the same method useful for the very same purpose is *prima facie* obvious. See *In re Kerkhoven* 205 USPQ 1069.

One of ordinary skill in the art would have motivated to incorporate the herein claimed excipients such as petrolatum, carbomer, triethanolamine, propylene glycol, and mineral oil into the composition of treating dry skin because petrolatum, carbomer, triethanolamine, propylene glycol, and mineral oil are common excipients useful for formulating topical composition. Therefore, incorporating known topical excipients into the topical composition of for treating dry skin would be reasonably expected to be effective.

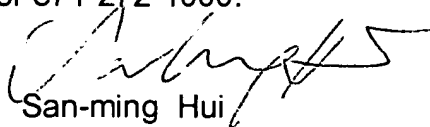
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No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


San-ming Hui
Primary Examiner
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